

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS

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IN RE: YASMIN AND YAZ	)	3:09-md-02100-DRH-PMF
(DROSPIRENONE) MARKETING, SALES	)	
PRACTICES AND PRODUCTS LIABILITY	)	MDL No. 2100
LITIGATION	)	
	)	

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This Document Relates to:

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**STEPHANIE BISHOP,**

**Plaintiff,**

v.

**3:10-cv-11716-DRH-PMF**

**BAYER CORPORATION, BAYER  
HEALTHCARE PHARMACEUTICALS,  
INC., BAYER SCHERING PHARMA AG,  
and BAYER AG,**

**Defendants.**

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**ANSWER AND ADDITIONAL DEFENSES OF  
DEFENDANT BAYER HEALTHCARE PHARMACEUTICALS INC.**

Defendant Bayer HealthCare Pharmaceuticals Inc. (“BHCP”), for its Answer to Plaintiff’s Complaint (the “Complaint”), states as follows:

In response to the unnumbered paragraph preceding paragraph 1, BHCP admits that BHCP sold YAZ® and Yasmin® in the United States, and that YAZ® and Yasmin® are oral contraceptives. BHCP denies that BHCP manufactured or designed YAZ® or Yasmin®. BHCP admits that YAZ® and Yasmin® contain ethinyl estradiol and drospirenone. BHCP denies the remaining allegations in the unnumbered paragraph preceding paragraph 1.

1. The allegations in paragraph 1 state conclusions of law to which no response is required. To the extent that a response is required, BHCP states that, on the face of the Complaint and assuming that Plaintiff is a citizen of the state in which Plaintiff is alleged to reside, this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 in that this is an action between citizens of different states and in which citizens of a foreign state are additional parties, with an amount in controversy allegedly exceeding \$75,000, exclusive of interest and costs. BHCP denies any remaining or inconsistent allegations in paragraph 1.

2. BHCP denies that any of Plaintiff's alleged injuries were caused by YAZ® or Yasmin®. BHCP is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 2.

3. BHCP admits that Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. BHCP denies the remaining allegations in paragraph 3.

4. BHCP admits that it is a Delaware corporation with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. BHCP admits that BHCP distributes, sells and markets YAZ® and Yasmin® in the United States. BHCP denies that BHCP develops, designs, licenses or manufactures YAZ® or Yasmin®. BHCP admits that it has sold and distributed its products in Illinois. Because of the vagueness and ambiguity of the remaining allegations in paragraph 4, BHCP is without knowledge or information sufficient to form a belief as to the truth of those allegations.

5. BHCP admits that BHCP was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and that BHCP is a Delaware corporation with its principal place of business in New Jersey. BHCP further admits that Berlex, Inc., formerly known as

Berlex Laboratories, Inc., had its principal place of business in Montville, New Jersey. BHCP denies the remaining allegations in the first and second sentences in paragraph 5. BHCP admits that BHCP, formerly known as Berlex, Inc., formerly known as Berlex Laboratories, Inc., distributed, sold and marketed YAZ® and Yasmin® in the United States. BHCP denies that BHCP, formerly known as Berlex, Inc., formerly known as Berlex Laboratories, Inc., developed, designed, licensed or manufactured YAZ® or Yasmin®. BHCP admits that BHCP, formerly known as Berlex, Inc., formerly known as Berlex Laboratories, Inc., has sold and distributed its products in Illinois. Because of the vagueness and ambiguity of the remaining allegations in paragraph 5, BHCP is without knowledge or information sufficient to form a belief as to the truth of those allegations.

6. BHCP admits that Bayer Schering Pharma AG is a German company with its principal place of business at Müllerstraße 178, 13353 Berlin, Germany. BHCP admits that Bayer Schering Pharma AG researched, developed and designed Yasmin® and YAZ®, that Bayer Schering Pharma AG manufactured drospirenone and ethinyl estradiol, which are the progestin and estrogen contained in Yasmin® and YAZ®, that Bayer Schering Pharma AG sold Yasmin® and YAZ® to BHCP, that Bayer Schering Pharma AG licensed, distributed and sold a generic equivalent of Yasmin® to Barr Laboratories, Inc., that Bayer Schering Pharma AG granted a license to Barr Laboratories, Inc. to market a generic equivalent of YAZ® effective at a later date, and that Yasmin® and YAZ® are prescription oral contraceptives. BHCP denies that Bayer Schering Pharma AG manufactured Yasmin® or YAZ® tablets. BHCP denies that Bayer Schering Pharma AG marketed Yasmin® or YAZ® in the United States. BHCP denies that Bayer Schering Pharma AG licensed Yasmin® or YAZ®, and denies that Bayer Schering Pharma AG licensed a generic equivalent of Yasmin® or YAZ® in the United States other than

to Barr Laboratories, Inc. BHCP denies that Bayer Schering Pharma AG sold Yasmin® or YAZ® to parties located in the United States other than BHCP, and denies that Bayer Schering Pharma AG sold a generic equivalent of Yasmin® to parties located in the United States other than Barr Laboratories, Inc. BHCP denies that Bayer Schering Pharma AG distributed Yasmin® or YAZ® in the United States and denies that Bayer Schering Pharma AG distributed a generic equivalent of Yasmin® in the United States other than to Barr Laboratories, Inc. Because of the vagueness and ambiguity of the remaining allegations in the second sentence in paragraph 6, BHCP is without knowledge or information sufficient to form a belief as to the truth of those allegations. BHCP denies the remaining allegations in paragraph 6.

7. The allegations in paragraph 7 state conclusions of law to which no response is required. To the extent that a response is required, BHCP admits that Bayer Schering Pharma AG was formerly known as Schering AG and that Bayer Schering Pharma AG is the same corporate entity as Schering AG. BHCP admits that Schering AG was renamed Bayer Schering Pharma AG. BHCP denies the remaining allegations in paragraph 7.

8. BHCP admits that Bayer Schering Pharma AG is the owner of all patents listed in the Orange Book for YAZ® and Yasmin®. BHCP denies any remaining allegations in paragraph 8.

9. BHCP denies the allegations in paragraph 9.

10. BHCP admits that Bayer AG is a German company with its headquarters in Leverkusen, North Rhine-Westphalia, Germany. BHCP denies the remaining allegations in paragraph 10.

11. BHCP admits that Bayer Corporation and Bayer Schering Pharma AG are wholly owned by Bayer AG and that BHCP and Bayer HealthCare LLC are indirectly owned by Bayer AG. BHCP denies the remaining allegations in paragraph 11.

12. BHCP denies the allegations in paragraph 12.

13. BHCP admits that the Complaint contains allegations referring to BHCP and other entities collectively as “Defendants” or otherwise, but BHCP is not answering the Complaint on behalf of any entity other than BHCP, and is not answering allegations that are directed to any entity other than BHCP. BHCP accordingly denies the allegations in paragraph 13.

14. BHCP denies the allegations in paragraph 14.

15. BHCP admits that drospirenone, a component of YAZ® and Yasmin®, may potentially increase potassium levels in the blood. BHCP denies that YAZ® or Yasmin® when used in accordance with the labeling is associated with clinically significant hyperkalemia or is associated with hyperkalemia at the level that can cause heart rhythm disturbances. BHCP further states that the labeling for YAZ® and Yasmin® provides appropriate warnings regarding the potential risks of hyperkalemia. BHCP admits that severe hyperkalemia from other causes may result in certain heart rhythm disturbances. BHCP denies the remaining allegations in paragraph 15.

16. BHCP admits that Yasmin® has been sold in the United States since 2001 and that YAZ® has been sold in the United States since 2006. BHCP further admits that since 2001, the FDA received MedWatch forms regarding women reportedly using YAZ® or Yasmin® in which adverse events were reported, including over fifty MedWatch forms regarding women reportedly using YAZ® or Yasmin® in which deaths were reported. For a further response, the submission of a MedWatch form to the FDA does not constitute an admission or assertion that

the use of YAZ® or Yasmin® caused or contributed to the event that is the subject of the MedWatch form. BHCP further responds that with respect to a number of the reports of adverse events including reports of deaths submitted to the FDA, the use of YAZ® or Yasmin® has not been confirmed. BHCP further responds that all birth control pills approved for use in the United States are associated with reports of adverse events including death, and that the labeling for YAZ® and Yasmin® provides appropriate warnings regarding the risks associated with the use of YAZ® and Yasmin®. BHCP denies the remaining allegations in paragraph 16.

17. BHCP admits that BHCP promoted YAZ® and Yasmin® in the United States. BHCP denies the allegations in paragraph 17 regarding the contents of any letters from the FDA to the extent that they are inconsistent with the language of the letters or omit portions of the letters. BHCP denies the remaining allegations in paragraph 17.

18. BHCP denies the allegations in paragraph 18.

**COUNT ONE**

19. BHCP incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

20. BHCP denies the allegations in paragraph 20.

21. BHCP denies the allegations in paragraph 21.

**COUNT TWO**

22. BHCP incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

23. The allegations in paragraph 23 state conclusions of law to which no response is required. To the extent that a response is required, BHCP denies that BHCP violated any applicable duty relating to YAZ® or Yasmin®. Because of the vagueness and ambiguity of the

remaining allegations in paragraph 23, BHCP is without knowledge or information sufficient to form a belief as to the truth of those allegations.

24. BHCP denies the allegations in paragraph 24.

25. BHCP denies the allegations in paragraph 25.

**COUNT THREE**

26. BHCP incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

27. BHCP admits that it sold YAZ® and Yasmin® in the United States. BHCP denies any remaining allegations in paragraph 27.

28. The allegations in paragraph 28 state conclusions of law to which no response is required. To the extent that a response is required, BHCP admits that BHCP marketed YAZ® and Yasmin® as safe for the indications approved by the FDA, when prescribed to patients by physicians in accordance with the labeling and prescribing information approved by the FDA. For a further response, BHCP states that BHCP provided appropriate warnings regarding the risks associated with the use of YAZ® and Yasmin®. BHCP denies the remaining allegations in paragraph 28.

29. BHCP denies the allegations in paragraph 29.

30. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding what Plaintiff relied upon. BHCP denies the remaining allegations in paragraph 30.

31. BHCP denies the allegations in paragraph 31.

**COUNT FOUR**

32. BHCP incorporates by reference its responses to all preceding paragraphs of the Complaint as if fully set forth herein.

33. BHCP admits that it sold YAZ® and Yasmin® in the United States. BHCP denies any remaining allegations in paragraph 33.

34. The allegations in paragraph 34 state conclusions of law to which no response is required. To the extent that a response is required, BHCP admits that BHCP marketed YAZ® and Yasmin® as safe for the indications approved by the FDA, when prescribed to patients by physicians in accordance with the labeling and prescribing information approved by the FDA. For a further response, BHCP states that BHCP provided appropriate warnings regarding the risks associated with the use of YAZ® and Yasmin®. BHCP denies the remaining allegations in paragraph 34.

35. BHCP denies the allegations in paragraph 35.

36. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding what Plaintiff relied upon. BHCP denies the remaining allegations in paragraph 36.

37. BHCP denies the allegations in paragraph 37.

38. BHCP denies that Plaintiff is entitled to any relief, including but not limited to the relief requested in the “Wherefore” clauses of the Complaint.

39. BHCP denies each and every allegation in the Complaint that relates to or is directed to BHCP unless such allegations are expressly admitted in this Answer.

### **ADDITIONAL DEFENSES**

Discovery and investigation may reveal that one or more of the following additional defenses should be available to BHCP in this matter. BHCP accordingly reserves the right to assert these separate and additional defenses. Upon completion of discovery, if the facts warrant, BHCP may withdraw any of these additional defenses as may be appropriate. BHCP further reserves the right to amend its Answer and defenses, and to assert additional defenses and other claims, as this matter proceeds.

Further answering, and by way of additional defense, BHCP states as follows:

1. Plaintiff's Complaint, and each and every count contained therein, fails to state a cause of action or claim upon which relief can be granted.
2. Some or all of Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statutes of repose.
3. Plaintiff's claims are barred, in whole or in part, by laches, waiver and/or estoppel.
4. Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to mitigate Plaintiff's alleged damages.
5. The acts and omissions of Plaintiff caused and/or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrines of contributory negligence and/or comparative negligence. Plaintiff's recovery, if any, therefore is barred or should be apportioned in accordance with applicable law.
6. The alleged injuries sustained by Plaintiff, if any, were caused, in whole or in part, by pre-existing physical, medical, and/or physiological conditions, for which BHCP has no legal responsibility.

7. If Plaintiff suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiff. Plaintiff's recovery accordingly is barred or should be reduced by Plaintiff's assumption of the risk.

8. If the injuries claimed by Plaintiff were related to the use of YAZ® and/or Yasmin®, which is expressly denied, any such injuries were the result of an idiosyncratic or allergic reaction to YAZ® and/or Yasmin®.

9. The injuries and damages claimed by Plaintiff, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of BHCP was not the proximate and/or competent producing cause of such alleged injuries and damages.

10. The injuries and damages claimed by Plaintiff, if any, are barred or must be reduced because those damages arose from the acts or omissions of persons or entities other than BHCP for whom BHCP has no legal responsibility.

11. If Plaintiff sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling or other unforeseeable misuse, or use inconsistent with the labeling of the prescription drugs YAZ® and/or Yasmin®. Plaintiff's recovery is accordingly barred.

12. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including BHCP.

13. Plaintiff's claims are barred because the benefits of YAZ® and Yasmin® outweigh the risks, if any, that might be associated with the products.

14. The claims in the Complaint are barred in whole or in part by the learned intermediary doctrine.

15. Plaintiff's Complaint fails to state a claim upon which relief can be granted in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of YAZ® and Yasmin®, including but not limited to adequate warnings and instructions with respect to the products' use included in the products' package inserts and other literature, conformed to the applicable state of the art. YAZ® and Yasmin®, including their labeling approved by the FDA, complied with the state of scientific and medical knowledge available at the time. Plaintiff's recovery accordingly is barred.

16. Plaintiff's claims are barred because YAZ® and Yasmin® were neither defective nor unreasonably dangerous in their design, manufacture or marketing and were reasonably safe and reasonably fit for their intended uses, thereby barring Plaintiff's recovery.

17. The warnings and instructions accompanying YAZ® and Yasmin® at the time of the occurrence or injuries alleged by Plaintiff were legally adequate warnings and instructions.

18. Plaintiff's claims are barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited to, § 402A, comment k.

19. BHCP gives notice that to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, BHCP intends to rely upon same in defense of this action.

20. The prescription drugs YAZ® and Yasmin® complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of these prescription drugs, and that they were neither defective nor unreasonably dangerous. Plaintiff's recovery is accordingly barred.

21. Any claims by Plaintiff relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government.

22. Plaintiff's claims are barred in whole or in part because the commercial speech relating to YAZ® and Yasmin® is protected under the First Amendment of the United States Constitution and the applicable state constitution.

23. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

24. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal regulation of prescription drug manufacturing, testing, marketing, and labeling.

25. Plaintiff cannot state a claim upon which relief may be granted with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

26. This Court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

27. Plaintiff did not detrimentally rely on any labeling, warnings or information concerning YAZ® and/or Yasmin®.

28. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

29. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

30. To the extent that Plaintiff's Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

31. To the extent that Plaintiff's claims have been settled or Plaintiff will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of BHCP, if any, should be reduced accordingly.

32. Plaintiff's claims may be barred, in whole or in part, due to res judicata, collateral estoppel, or by release of claims.

33. Plaintiff's Complaint fails to state a claim upon which relief can be granted as to costs or successor liability.

34. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

35. Plaintiff's Complaint fails to state a claim upon which relief can be granted for several or joint and several liability.

36. Plaintiff's claims for breach of warranty are barred because Plaintiff failed to give timely notice of any alleged breach of warranty.

37. BHCP did not sell or distribute YAZ® or Yasmin® directly to Plaintiff, and Plaintiff did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiff's claims for breach of warranty are barred by lack of privity between Plaintiff and BHCP.

38. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable state's Uniform Commercial Code or other applicable law.

39. This Court is an improper venue for the trial of this action.

40. This Court is not the proper forum for the trial of this action and is not a convenient forum for the just adjudication of Plaintiff's claims.

41. Plaintiff's causes of action are barred in whole or in part and the recoverable damages, if any, should be diminished pursuant to Article 14-A of the New York Civil Practice Law and Rules, because the fault, negligence and culpable conduct of parties or non-parties over whom BHCP has no control and no responsibility caused or contributed to the injuries and damages allegedly sustained.

42. The equitable share of liability, if any, of BHCP shall be determined pursuant to the provisions of Article 16 of the New York Civil Practice Law and Rules.

43. The recoverable damages, if any, should be diminished under the collateral source rule, New York Civil Practice Law and Rules § 4545.

44. Pursuant to New York General Obligations Law § 15-108, to the extent that Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of BHCP, if any, should be reduced accordingly.

45. If the pharmaceutical products YAZ® and/or Yasmin® were unsafe, which BHCP expressly denies, they were unavoidably unsafe. The apparent benefits of these pharmaceutical products also exceed any apparent risks given the scientific knowledge available when the products were marketed.

46. BHCP adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with BHCP's defenses pleaded in this Answer.

WHEREFORE, BHCP requests that Plaintiff's Complaint be dismissed with prejudice, that judgment be entered in favor of BHCP and against Plaintiff, and that BHCP be awarded the costs of this action, together with such other and further relief as may be appropriate.

**JURY DEMAND**

BHCP hereby demands a trial by jury on all issues so triable.

*s/ Terry Lueckenhoff*  
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*s/ Adam Hoeflich (w/ consent)*  
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*Attorneys for Defendant Bayer HealthCare  
Pharmaceuticals Inc.*

Dated: September 28, 2010

**CERTIFICATE OF SERVICE**

I hereby certify that on September 28, 2010, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all attorneys of record.

s/Terry Lueckenhoff